REMARKS

Applicants wish to thank the Examiner for examination of the present application. In this response, claims 1, 12, 15-17, 27-29, 32, 34-38, 40 and 42-46 have been amended; claims 18, 30, 31, 39, 41, 47 and 48 have been cancelled; and claims 49-56 have been added. Independent claims 1, 27 and 28 have been amended to include subject matter appearing in the presently cancelled claims. For example, each of independent claims 1, 27 and 28 as presently amended requires *a condylar bone-facing implant surface that includes, at least in part, a planar surface to abut a bone cut surface of the patient's condyle*. Moreover, each of claims 1, 27 and 28 as presently amended also requires *a condylar articular implant surface that includes, at least in part, a curvature that substantially replicates the curvature of at least a portion of an uncut articular surface of the patient's femoral condyle*.

In addition, independent claims 1, 27 and 28 have been amended for organization and grammar. For example, section structure has been amended and alphanumeric section headings have been added for organization. Certain terms have been added for grammar. For example, *condylar portion* and *trochlear portion* have been added for grammar. In addition, certain terms have been amended for grammar. For example, *joint-facing implant surface* has been amended to *articular implant surface*, and *match* has been amended to *replicates*, for grammar.

Dependent claims 12, 15-17, 29, 32, 34-38, 40 and 42-46 have been amended for consistency with the present amendments to independent claims. New dependent claim 49 has been introduced to recite that a tibial implant component provides the tibial surface recited in claim 1. New dependent claim 50 has been introduced to recite that the replicated shape of a portion of uncut articular surface refers to an uncut adjacent bone surface. New dependent claims 51-54 recite optional numbers and

characteristics of the one or more condylar portions recited in independent claim 28. In addition, specification paragraphs [0101], [0119], [0153], and [0159] have been amended to correct typographical errors.

Support for these amendments and new claims appears throughout the application. (See, for example, Application, FIGS. 2A, 2C-2E, 4A-4H, 5A-5N, 6A-6G; Paragraphs [0038], [0068], [0071], [0074], [0082], [0089], [0096], [0101] and [0112]; and the originally filed claims.) Applicants believe that these amendments and new claims introduce no new matter. Upon entry of this response, claims 1, 3-17, 19-29, 32-38, 40, 42-46 and 49-56 are pending in the application.

35 U.S.C. §102 and §103

Claims 1, 3-5, 8, 11-14, 16-26, 28-31 and 34-48 stand rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,712,856 (Carignan). In addition, claims 6, 7, 9, 10, 32, and 33 stand rejected under 35 U.S.C. §103 over Carignan in view of U.S. Patent Application Publication 2003/0060882 (Fell) and claims 15 and 27 stand rejected under 35 U.S.C. §103 over Carignan in view of U.S. Patent Application Publication 2004/016730 (Rolston).

Claims 16, 18, 30, 31, 39, 41, 47 and 48 have been cancelled thereby rendering as moot the rejections against these claims.

Carignan fails to teach or suggest each and every element of Applicants amended claims. For example, each of pending independent claims 1, 27, and 28 has been amended to require, among other things, an implant having *a condylar bone-facing implant surface that includes, at least in part, a planar surface to abut a bone cut surface of a patient's condyle*. Carignan fails to teach or suggest this element of each independent claim and, by dependency, each dependent claim. Rather, Carignan describes a trochlear resurfacing device that does not employ a bone cut. In particular, Carignan

describes a device having a "bottom" trochlear surface that is matched to an adjacent trochlear surface of a femur. Carignan does not disclose a device having *a bone-facing surface with a planar portion to abut a bone cut surface of a patient's condyle*, as required by Applicants' amended claims. In fact, Carignan expressly teaches against removal of tissue, and, thus, neither anticipates nor renders obvious the amended claims:

> Insertion of the replacement device requires minimal removal of existing anatomic structures, if at all. Therefore, the intent is to remove only the diseased portion (the natural cartilage) of the patient's knee joint prior to installing the replacement device. (Carignan, Col. 7, lines 4-8.)

Additionally, each of pending independent claims 1, 27, and 28 have been amended to require, among other things, *a condylar articular implant surface that includes, at least in part, a curve that substantially replicates or approximates a curvature of at least a portion of an uncut articular surface of a patient's femoral condyle.* Carignan does not teach or suggest this element of the amended claims. Carignan instead describes a device in which the articular surface, which is referred to as the "top surface", only replicates a "tracking-pattern" of the trochlear groove. As defined by Carignan, the tracking-pattern is a linear direction and not a curvature of any kind. Carignan expressly defines the tracking-pattern as an "axis t-t". This straight-line axis is clearly shown in FIG. 3 of Carignan and explained at Col. 6, lines 17-23. (See also more generally the associated explanation of the two methods used to determine the tracking pattern at Carignan, Col. 6, lines 5-37.)

Furthermore, Carignan actually discloses an articular surface that does ***not*** replicate or approximate the curvature of the underlying joint surface of the patient. Carignan expressly states that the outer surface has an "increased curvature." (See generally Col. 6, lines 38-62.) As Carignan explains, this is because the top surface of the device is designed to accommodate a standard off-the-shelf device. More

specifically, Carignan is designed merely to articulate with a standardized patellar replacement device. For example, Carignan explains that the lip regions of the outer surface of the device have an increased curvature, and that this increased curvature is included in order to accommodate "a standard dome patellar prosthesis 30 such as the Kinamed, Inc. GEM Knee System patella []." (Carignan, Col. 6, lines 48-50.) Thus, the top surface is not designed to substantially replicate or approximate the natural curvature of the patient's anatomy.

The fact that the top surface of Carignan does not replicate or approximate the curvature of the patient's joint anatomy is further corroborated, and clearly shown, by FIG. 5 of Carignan, which shows a cross-section along a center-line 5-5 of the implant (as referenced in FIG. 2 of Carignan).

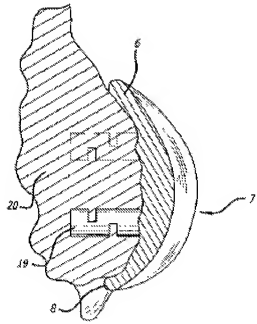

FIG. 5

As shown in FIG. 5, even the lowest part of the trochlear groove on the top surface does not substantially replicate or approximate the underlying curvature of the patient's bone. The top surface neither exactly matches the patient's bone as does the bottom surface nor does it provide a smooth replication or approximation of the curvature by eliminating localized irregularities of the undersurface. Rather, consistent with the description cited above, the curvature along the center line of the device as shown is increased when compared to the underlying bone, being much thicker in the middle of the implant than along the edges, and sloping significantly throughout the length of the implant along the sagittal plane shown in FIG. 5. Also as shown and also consistent with the explanation cited above, the lips or edges of the implant have an even more exaggerated curvature than the central groove portion.

Thus, in view of at least each of these two exemplary elements of Applicants' amended claims, Carignan cannot anticipate Applicants' claims. Furthermore, for at least the reasons described above, Carignan cannot render obvious the devices claimed in the present application, because the outer surface of Carignan has a very different structure and serves a very different function than the condylar articular surface claimed in the present application.

Neither Fell nor Rolston cure the deficiencies in Carignan. Fell describes a unicompartmental interpositional spacer for placement between the femur and tibia without any bone resection or mechanical fixation. Rolston describes a bicompartmental arthroplasty device having standard, off-the-shelf interior and exterior surfaces. Neither describes, for example, a patient-specific implant, including a patient specific device having an articular surface that replicates the curvature of the uncut articular surface of the patient's condyle, as in the amended claims.

Thus, Applicants' claims cannot be obvious in view of any combination of Carignan, Fell, and/or Rolston.

Applicants reserve all other arguments with respect to the Examiner's rejections, including any argument that Applicants may have invented the claimed subject matter earlier than the priority date of any one or more of Carignan, Fell, and Rolston.

Conclusion

It is submitted that the application is in condition for allowance and Applicants respectfully request issuance of a notice of allowance. It is believed that a two month extension of time is required. Applicants respectfully petition for any required extension. Authorization is hereby given to charge deposit account number 19-4972. If any additional fees are required for the timely consideration of this application, please charge deposit account number 19-4972.

Applicants request that the undersigned, Alexander J. Smolenski, Jr., be contacted if it will assist further examination of this application.

Respectfully submitted,

/Alexander J. Smolenski, Jr., #47,953/

Alexander J. Smolenski, Jr.
Registration No. 47,953
Attorneys for Applicants

Sunstein Kann Murphy & Timbers LLP
125 Summer Street
Boston, MA 02110-1618
(617) 443-9292

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